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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/547,220	04/11/2000	Michael Brines	10165-006-999	4714

20583 7590 10/22/2002

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EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/22/2002 16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/547,220	BRINES ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Status of Application, Amendments and/or Claims

The amendment filed 14 August 2002 (Paper No. 15) has been entered in full. New claims, 35-39 have been added. The information disclosure statement filed 14 August 2002 (Paper No. 15) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection to the specification as set forth at page 3 of the previous Office Action (13 June 2002, Paper No. 14) is *withdrawn* in view of the amendment (14 August 2002, Paper No. 15).

The rejection of claims 28 and 32 under 35 U.S.C. 112, second paragraph as set forth at page 5 of the previous Office Action (13 June 2002, Paper No. 14) is *withdrawn* in view of the amendment (14 August 2002, Paper No. 15).

The rejection of claim 32 under 35 U.S.C. 112, first paragraph as set forth at pages 3-5 of the previous Office Action (13 June 2002, Paper No. 14) is *withdrawn* in view of Applicant's arguments (14 August 2002, Paper No. 15).

The rejection of claims 28-31, 33 and 34 under 35 U.S.C. 102(b) as being anticipated by Grimm *et al.* (IDS#BC, Paper No. 4) as set forth at page 6 of the previous

Office Action (13 June 2002, Paper No. 14) is *withdrawn* in view of Applicant's arguments (14 August 2002, Paper No. 15).

Claim Rejections - 35 USC § 112, scope of enablement

Claims 28-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: a method for treating cerebral ischemia in a mammal comprising peripherally administering to said mammal an amount of EPO that does not increase hemoglobin concentration or hematocrit in said mammal effective to exert a neuroprotective effect

and a method for treating cerebral ischemia in a human comprising peripherally administering to said human an amount of EPO that does not increase hemoglobin concentration or hematocrit in said human effective to exert a neuroprotective effect, does not reasonably provide enablement for a method for treating cerebral ischemia in a mammal or human comprising peripherally administering to said mammal or human *a* ***non-toxic amount*** of erythropoietin to said mammal or human effective to exert a neuroprotective effect. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or the invention commensurate in scope with these claims.

The instant claims recite "non-toxic amounts" which can encompass different quantities of EPO, however the claims are only enabled for EPO amounts that do not increase hemoglobin concentration or hematocrit because increases in hemoglobin or hematocrit have been shown to cause detrimental effects in patients. Severe

complications, such as hypertension, strokes or seizures can occur in patients receiving high doses of EPO over longer periods of time versus a bolus injection of EPO.

Due to the large quantity of experimentation necessary to safely treat cerebral ischemia in a mammal with EPO amounts that raise hemoglobin concentration or hematocrit, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention and the breadth of the claims which fail to recite limitations regarding EPO amounts that do not increase hemoglobin concentration or hematocrit, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, second paragraph

Claims 28 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "non-toxic amount" is ambiguous term and therefore the metes and bounds of the instant claims cannot be determined.

Matter of Record

Marsh teaches that recombinant human EPO treatment improves brain and cognitive function of anemic dialysis patients (Marsh *et al.* Kidney International, Vol. 39 pages 155-163, 1991, cited in IDS#BP, Paper No. 6). Grimm teaches that administering recombinant human erythropoietin in hemodialysis patients can improve brain function

(Grimm *et al.* Kidney International, Vol. 38 (1990) pages 480-486, cited in IDS#BC, Paper No. 6). The art is made of record but not relied upon because both inventors teach long term administration of EPO that raises hemoglobin and hematocrit levels.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD

RMD
October 18, 2002

Gary d. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600